

REMARKS

I. Introduction

In view of the following remarks, re-examination and re-consideration of the application, is requested.

II. Prior Art Rejections

In paragraph (1) of the Office Action, claims 1, 3-6, 8-9, and 37-41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gu et al., World Journal of Microbiology and Biotechnology (Gu) in view of Steinberg et al, Biodegradation (Steinberg). In paragraph (2) of the Office Action, claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over Gu and Steinberg as applied to claim 1, and further in view of Schrier et al., U.S. Patent No. 6,197,598 (Schrier). In paragraph (3) of the Office Action, claim 36 was rejected under 35 U.S.C. §103(a) as being unpatentable over Gu and Steinberg as applied to claim 1 and further in view of Cioanta et al., U.S. Publication No. 2002/0082556 (Cioanta).

Applicant respectfully traverses these rejections. In the sections below, Applicants' attorney reviews the properties of different lectins, the invention disclosed in the Gu, and the invention recited in the claims as amended hereinabove. Applicants' attorney then identifies portions of the M.P.E.P. and the associated case law that confirm that the disclosure in Gu cannot be combined with any reference (e.g. Schrier and/or Cioanta) in a manner that would have rendered the invention recited in Applicants' claims obvious.

1. LECTINS, THE CITED REFERENCES AND THE CLAIMED INVENTION

A. LECTINS

As is known in the art, lectins are a diverse group of proteins found principally in plant seeds that are observed to exhibit diverse properties. For example, some lectins can cause the agglutination of blood cells while other lectins can stimulate the proliferation of lymphocytes. Similarly, some lectins are observed to block adhesion of bacteria on surfaces while other lectins are observed to enhance the adhesion of bacteria on surfaces.

B. THE GU REFERENCE

Gu et al., PROTECTION OF CATHETER SURFACES FROM ADHESION OF *PSEUDOMONAS AERUGINOSA* BY A COMBINATION OF SILVER IONS AND LECTINS, World Journal of Microbiology and Biotechnology, 17: 173-179 (2001) teaches that lectins coated surfaces of medical devices protect these devices from being bound by bacteria such as *Pseudomonas aeruginosa*. At page 177, Gu teaches that these results are due to surface adhesion blockage by lectins and that the mechanism is believed to involve the blocking of binding sites by lectins that are otherwise available for bacterial exopolysaccharides.

C. THE CLAIMED INVENTION

The pending claims recite medical devices having a surface coated with a composition comprising a lectin having a specific subset of properties, namely an ability to bind a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device so as to enhance attachment of the microorganism to the composition comprising the lectin. In this embodiment of the invention, the lectin is disposed within a biodegradable polymer composition that can slough away from the surface of the medical device when the lectin is bound to the compound produced by a microorganism, so as to inhibit formation of a biofilm on the surface of the medical device.

3. RESPONSE TO REJECTIONS UNDER 35 U.S.C. §103(a)

The outstanding rejection under 35 U.S.C. §103(a) is predicated on the Patent Office's assertions that "Gu also discloses lectins may be used to enhance adhesion of bacteria that form biofilms (Page 177)" and "[t]herefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gu to give the lectins improved adhesive properties as taught by Gu itself so as to improve biofilm inhibition of the device as known in the art via Steinberg" (as articulated in the paragraph bridging pages 2-3 of the outstanding Office Action). Applicants respectfully traverse this rejection because it is contrary to case law relating to determinations of obviousness under 35 U.S.C. §103(a) (e.g. as found in case law identified in M.P.E.P. 2145(X)(D)(2)).

As noted for example in *KSR v. Teleflex*, 550 U.S. ___, 127 S. Ct. 1727 (2007), in determinations of obviousness under 35 U.S.C. §103(a), there must be some motivation to combine

references. M.P.E.P. 2144 notes that prior art used in such determinations of obviousness must be viewed “as a whole”, including those portions that lead away from the claimed invention (see, e.g. In re Langer, 465 F.2d 896, 175 USPQ 169 (CCPA 1972); and *Gore & Assoc. Inc. v. Garlock Inc.* 220 USPQ 303 (Fed. Cir. 1983)). In this context, the disclosure in Gu on page 177 that is relied upon by the Patent Office to make this rejection specifically notes that “Lectins are highly specific in blocking or enhancing adhesion of bacteria on surface and, in comparison, the glycoconjugates in the bacterial exopolysaccharides are not yet known for their role in the adhesion and deadhesion process”. This single statement at page 177 of Gu **(one that merely describes well-known properties of lectins) is the only text in this article that mentions the existence of lectins that can enhance the adhesion of bacteria.** Consequently, the Gu disclosure fails to teach or suggest any use whatsoever for lectins having adhesive properties. In contrast however, **the Gu article teaches the use of lectins to block bacterial adhesion on medical devices at least 16 times** throughout this disclosure. Consequently, the Patent Office’s rejection, one that focuses on a single vague statement while disregarding the at least 16 statements that lead artisans in a direction divergent from the path that was taken by the Applicant, fails to comply with the provisions of patent law by viewing the disclosure in Gu “as a whole”.

M.P.E.P. 2145(X)(D)(2) explicitly notes that references cannot be combined in situations where a reference teaches away from their combination. In this context, a reference (viewed as a whole) teaches away from an invention when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant (see, e.g. In re Gurley, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130 (Fed. Cir. 1994)). In view of this case law, Applicants respectfully traverse the rejection under 35 U.S.C. §103(a) because the skilled artisan would not, as the Patent Office believes, disregard the at least 16 statements in the Gu disclosure that describe the use of lectins to inhibit bacterial attachment to medical devices to instead focus on the single general statement at page 177 to provide a motivation to combine this disclosure with another reference (e.g. Schrier and/or Cioanta) in a manner that would have rendered the invention recited in Applicants’ claims obvious. As noted below, the skilled artisan would instead be led in a direction divergent from the path that was taken by the Applicant.

As noted above, viewing the disclosure in Gu as a whole, it is clear that this article teaches that medical devices can be coated with lectins in order to block bacterial adhesion. This is the opposite direction from the path that was taken by the Applicant. Consequently, as a whole this reference teaches away the invention recited in Applicants' claims, one that comprises lectins that exhibit a specific subset of properties, namely an ability to bind a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device so as to enhance attachment of the microorganism to the composition comprising the lectin. Because Gu teaches away from the invention recited in Applicant's claims as amended hereinabove, it cannot be combined with any other reference (e.g. Schrier and/or Cioanta) in a manner that renders the invention recited in these amended claims obvious (see, e.g. M.P.E.P. 2145(X)(D)(2)). For this reason, the Applicant respectfully requests the withdrawal of the rejection under 35 U.S.C. §103(a).

Moreover, the various elements of Applicants' claimed invention together provide operational advantages over Gu, Schrier and/or Cioanta. In addition, Applicants' invention solves problems not recognized by Gu, Schrier and/or Cioanta. Thus, Applicants submit that independent claims 1 and 38 are allowable over Gu, Schrier and/or Cioanta. Further, dependent claims 3-9, 36, 37, and 39-41 are submitted to be allowable over Gu, Schrier and/or Cioanta in the same manner, because they are dependent on independent claims 1 and 38 respectively, and thus contain all the limitations of the independent claims. In addition, dependent claims 3-9, 36, 37, and 39-41 recite additional novel elements not shown by Gu, Schrier and/or Cioanta.

III. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicant's undersigned attorney.

Respectfully submitted,

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Date: May 26, 2009

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G&C 130.62-US-01